IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
RANBAXY LABORATORIES LTD. RANBAXY INC. and RANBAXY PHARMACEUTICALS INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Mallinckrodt LLC ("Mallinckrodt"), for their Complaint against Defendants Ranbaxy Laboratories Limited ("RLL"), Ranbaxy Inc., and Ranbaxy Pharmaceuticals Inc. ("RPI") (collectively, "Defendants" or "Ranbaxy"), allege as follows:

PARTIES

1. Plaintiff Endo is a Delaware corporation, having its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo is a specialty pharmaceuticals company engaged in the research, development, sale and marketing of prescription pharmaceuticals used, among other things, to treat and manage pain. Endo markets and distributes OPANA® ER, an innovative opioid painkiller designed to be crush-resistant (alternatively referred to herein as "Opana ER CRF").

2. Plaintiff Mallinckrodt is a Delaware company, having its principal place of business at 675 McDonnell Blvd., St. Louis, Missouri 63042. Mallinckrodt manufactures and distributes products used in diagnostic procedures and in the treatment of pain and related conditions.

3. Defendant RLL is an Indian corporation, organized and existing under the country of India, and having its headquarters and principal place of business at Village Toansa, Rail Majra, Nawanshahr, India, 144533.

4. Upon information and belief, RLL is an international pharmaceutical company engaged in the development, manufacture, distribution, sale and marketing of pharmaceuticals for sale and use in over 150 countries around the world and throughout the United States, including in this judicial district.

5. Defendant Ranbaxy Inc. is a wholly-owned subsidiary of RLL organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 600 College Road East, Suite 2100, Princeton, NJ 08540.

6. Upon information and belief, Ranbaxy Inc. is the North American commercial arm of RLL, which is engaged in the development, manufacture, distribution, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

7. Defendant RPI is a wholly-owned subsidiary of RLL organized and existing under the laws of the State of Florida, having its principal place of business at 9431 Florida Mining Boulevard East, Jacksonville, FL 32257.

8. Upon information and belief, RPI is a generic pharmaceutical company engaged in the development, manufacture, distribution, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

9. Upon information and belief, RLL controls and directs the operations of Ranbaxy Inc. and RPI, and together all three companies have acted as each other's alter ego, agent, and

partner in the development and preparation of Abbreviated New Drug Application ("ANDA") Nos. 20-3506 and 20-4527 for generic oxymorphone extended release tablets.

NATURE OF ACTION

10. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*. and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement), and 28 U.S.C. §§ 2201 and 2202 (declaratory judgment).

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

13. Defendant Ranbaxy, Inc. is a Delaware corporation and, therefore, is subject to personal jurisdiction in Delaware.

14. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, they have committed—or aided, abetted, planned, contributed to, or participated in the commission of—tortious conduct which will lead to foreseeable harm and injury to Endo and Mallinckrodt in the State of Delaware.

15. Upon information and belief, Ranbaxy has submitted to FDA paperwork purporting to constitute an Abbreviated New Drug Application under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) ("ANDA No. 20-3506"), seeking approval to engage in the commercial manufacture, use, and sale of 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxymorphone hydrochloride extended-release tablets, ("Ranbaxy's Generic Oxymorphone ER Tablets"), as a generic version of the drug described in Endo's Supplemental New Drug Application ("sNDA") 201655.

16. Upon information and belief, Defendants intend to distribute and sell Ranbaxy's Generic Oxymorphone ER Tablets in this judicial district should ANDA No. 20-3506 be approved by FDA.

17. Upon information and belief, Ranbaxy has submitted to FDA paperwork purporting to constitute an Abbreviated New Drug Application under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) ("ANDA No. 20-4527"), seeking approval to engage in the commercial manufacture, use, and sale of 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxymorphone hydrochloride extended-release tablets, ("Ranbaxy's ANDA Products"), as a generic version of the drug described in Endo's Supplemental New Drug Application ("sNDA") 201655.

18. Upon information and belief, Defendants intend to distribute and sell Ranbaxy's ANDA Products in this judicial district should ANDA No. 20-4527 be approved by FDA.

19. Moreover, Defendants maintain continuous and systematic contacts with the State of Delaware and this District.

20. Upon information and belief, Defendants currently sell significant quantities of over fifty (50) different generic drug products in this District. Those products include, for example, generic versions of Lipitor® and Imitrex® CD. Defendants publish a list of generic products manufactured and sold by Ranbaxy in the United States at http://www.ranbaxy.com/us/products/generic-products.

21. Furthermore, Ranbaxy has been sued as a patent infringer in this Court, and has declined to contest that this Court has personal jurisdiction over it. *See, e.g., Forest Labs., Inc. v. Ranbaxy Inc.*, No. 13-cv-1607-SLR; *Acura Pharms., Inc. v. Ranbaxy Inc.*, No. 13-cv-750-RGA.

22. Based on the facts and causes alleged herein, and for additional reasons to be developed through discovery, this Court has personal jurisdiction over Defendants.

FACTUAL BACKGROUND

The Drug Approval Process

23. A company seeking to market a new drug in the United States must first obtain approval from FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a).

24. On the other hand, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an ANDA. *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "reference listed drug" or "branded drug").

Endo's Opana ER CRF NDA

25. On December 12, 2011, FDA approved Endo's sNDA 201655 under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), for a new dosage form of Opana ER, which is a crush-resistant tablet that contains oxymorphone hydrochloride for the relief of pain (hereinafter, "Opana ER CRF").

26. Opana ER CRF is distributed and sold throughout the United States for relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

THE '737 PATENT

27. On August 19, 2014, the PTO duly and legally issued U.S. Patent No. 8,808,737 ("the '737 Patent"), entitled "Method of Treating Pain Utilizing Controlled Release

Oxymorphone Pharmaceutical Compositions and Instruction on Dosing for Renal Impairment" to Endo Pharmaceuticals Inc. as assignee. Harry Ahdieh is named as the inventor. A true and correct copy of the '737 Patent is attached as Exhibit A.

28. Endo is the sole owner and assignee of the '737 Patent.

29. Opana ER CRF is covered by one or more claims of the '737 Patent.

30. Endo has submitted patent information regarding the '737 Patent for listing by the FDA in the Orange Book. Upon information and belief, the FDA has or will list the '737 Patent in the Orange Book for Opana ER CRF.

THE '779 PATENT

31. On October 28, 2014, the PTO duly and legally issued U.S. Patent No. 8,871,779 ("the '779 Patent"), entitled "Process for Preparing Morphinan-6-One Products with Low Levels of α,β-Unsaturated Ketone Compounds" to Mallinckrodt as assignee. Henry J. Buehler, William E. Dummitt, Anthony Mannino, Dennis C. Aubuchon, and Hong Gu are named as inventors. A true and correct copy of the '779 Patent is attached as Exhibit B.

32. Mallinckrodt is the assignee and owner of the '779 Patent.

33. Endo has an exclusive license to the '779 Patent from Mallinckrodt in the appropriate field of use, including the exclusive right to enforce the '779 Patent in that field.

34. Opana ER CRF is covered by one or more claims of the '779 Patent.

35. Endo has submitted patent information regarding the '779 Patent for listing by the FDA in the Orange Book. Upon information and belief, the FDA has or will list the '779 Patent in the Orange Book for Opana ER CRF.

RANBAXY'S FIRST ANDA FILING

36. Upon information and belief, some time before December 28, 2011, Ranbaxy submitted to FDA paperwork purporting to constitute an Abbreviated New Drug Application

(ANDA No. 20-3506) under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxymorphone hydrochloride extended-release tablets ("Ranbaxy's Generic Oxymorphone ER Tablets"), as a generic version of the products described in sNDA 201655

37. Upon information and belief, Defendants plan to market and sell Ranbaxy's Generic Oxymorphone ER Tablets as a generic substitute for and in competition with OPANA® ER CRF.

38. Defendants' marketing and sale of Ranbaxy's Generic Oxymorphone ER Tablets will cause wholesale drug distributors, prescribing physicians and pharmacies to purchase, prescribe, and dispense it in competition with and as a substitute for OPANA® ER CRF.

39. Defendants' manufacture and sale of Ranbaxy's Generic Oxymorphone ER Tablets will cause Endo to suffer immediate and irreparable harm, including without limitation, irreparable injury to its business reputation and goodwill, lost sales of OPANA® ER CRF, the loss of the benefit of its investment in developing OPANA® ER and the reformulated crush-resistant version of OPANA® ER, and price erosion for OPANA® ER CRF.

RANBAXY'S SECOND ANDA FILING

40. Upon information and belief, some time before October 30, 2013, Defendants submitted to FDA paperwork purporting to constitute an Abbreviated New Drug Application (ANDA No. 20-4527) under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxymorphone hydrochloride extended-release tablets ("Ranbaxy's ANDA Products"), as a generic version of the products described in sNDA 201655.

41. Upon information and belief, Defendants plan to market and sell Ranbaxy's ANDA Products as a generic substitute for and in competition with OPANA® ER CRF.

42. Defendants' marketing and sale of Ranbaxy's ANDA Products will cause wholesale drug distributors, prescribing physicians and pharmacies to purchase, prescribe, and dispense it in competition with and as a substitute for OPANA® ER CRF.

43. Defendants' manufacture and sale of Ranbaxy's ANDA Products will cause Endo to suffer immediate and irreparable harm, including without limitation, irreparable injury to its business reputation and goodwill, lost sales of OPANA® ER CRF, the loss of the benefit of its investment in developing OPANA® ER and the reformulated crush-resistant version of OPANA® ER, and price erosion for OPANA® ER CRF.

44. Pursuant to its ANDA, Ranbaxy is seeking FDA approval to make, use, and sell its ANDA Products prior to expiration of the '737 and '779 Patents.

ENDO'S COUNT I: INFRINGEMENT OF THE '737 PATENT

45. Endo incorporates each of paragraphs 1-44 above as if set forth fully herein.

46. The submission of Ranbaxy's ANDA No. 20-3506 to FDA constitutes infringement of the '737 Patent under 35 U.S.C. § 271(e)(2)(A).

47. Ranbaxy is seeking FDA approval to engage in the commercial manufacture, use, or sale of Ranbaxy's Generic Oxymorphone ER Tablets before expiration of the '737 Patent. On information and belief, if granted approval, Ranbaxy intends to launch Ranbaxy's Generic Oxymorphone ER Tablets before expiration of the '737 Patent.

48. Any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's Generic Oxymorphone ER Tablets before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce

physicians and patients to infringe the ’737 Patent by performing all of the recited steps of one or more of claims 1–6 of the ’737 Patent.

49. Any such launch by Ranbaxy of Ranbaxy’s Generic Oxymorphone ER Tablets before expiration of the ’737 Patent would cause Endo to suffer immediate and irreparable harm.

ENDO’S COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’737 PATENT

50. Endo incorporates each of paragraphs 1-49 above as if set forth fully herein.

51. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. There is an actual case or controversy such that the Court may entertain Endo’s request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

53. Ranbaxy has made and will continue to make substantial preparation in the United States to manufacture, offer to sell, and sell Ranbaxy’s Generic Oxymorphone ER Tablets before expiration of the ’737 Patent.

54. Ranbaxy’s actions indicate its intention to manufacture, offer to sell, and sell Ranbaxy’s Generic Oxymorphone ER Tablets before expiration of the ’737 Patent, and further indicate a refusal to change the course of its action in the face of acts by Endo.

55. Any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy’s Generic Oxymorphone ER Tablets before expiration of the ’737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the ’737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce physicians and patients to infringe the ’737 Patent by performing all of the recited steps of one or more of claims 1–6 of the ’737 Patent.

56. Endo is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's Generic Oxymorphone ER Tablets by Ranbaxy before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent.

ENDO AND MALLINCKRODT'S COUNT III:
INFRINGEMENT OF THE '779 PATENT

57. Endo and Mallinckrodt incorporate each of paragraphs 1-44 above as if set forth fully herein.

58. The submission of Ranbaxy's ANDA No. 20-3506 to FDA constitutes infringement of the '779 Patent under 35 U.S.C. § 271(e)(2)(A).

59. Ranbaxy is seeking FDA approval to engage in the commercial manufacture, use, or sale of Ranbaxy's Generic Oxymorphone ER Tablets before expiration of the '779 Patent. On information and belief, if granted approval, Ranbaxy intends to launch Ranbaxy's Generic Oxymorphone ER Tablets before expiration of the '779 Patent.

60. Any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's Generic Oxymorphone ER Tablets before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent under 35 U.S.C. § 271(a)-(c).

61. Any launch by Ranbaxy of its Generic Oxymorphone ER Tablets before expiration of the '779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

62. Upon information and belief, Defendants are aware of the existence of the '779 Patent, and are aware that the commercial manufacture, sale, and offer for sale of Ranbaxy's Generic Oxymorphone ER Tablets constitutes infringement of the '779 Patent.

ENDO AND MALLINCKRODT'S COUNT IV:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '779 PATENT

63. Endo and Mallinckrodt incorporate each of paragraphs 1-44 and 57-62 above as if set forth fully herein.

64. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

65. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

66. Ranbaxy has made and will continue to make substantial preparation in the United States to manufacture, offer to sell, and sell Ranbaxy's Generic Oxymorphone ER Tablets before expiration of the '779 Patent.

67. Ranbaxy's actions indicate its intention to manufacture, offer to sell, sell and/or import Ranbaxy's Generic Oxymorphone ER Tablets before expiration of the '779 Patent.

68. Any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's Generic Oxymorphone ER Tablets before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent under 35 U.S.C. § 271(a)-(c).

69. Any launch by Ranbaxy of its Generic Oxymorphone ER Tablets before expiration of the '779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

70. Plaintiffs are entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's Generic Oxymorphone ER Tablets by

Ranbaxy before expiration of the ’779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the ’779 Patent.

ENDO’S COUNT V: INFRINGEMENT OF THE ’737 PATENT

71. Endo incorporates each of paragraphs 1-44 above as if set forth fully herein.

72. The submission of Ranbaxy’s ANDA No. 20-4527 to FDA constitutes infringement of the ’737 Patent under 35 U.S.C. § 271(e)(2)(A).

73. Ranbaxy is seeking FDA approval to engage in the commercial manufacture, use, or sale of Ranbaxy’s ANDA Products before expiration of the ’737 Patent. On information and belief, if granted approval, Ranbaxy intends to launch its ANDA Products before expiration of the ’737 Patent.

74. Any commercial manufacture, use, offer for sale, sale, and/or importation of Rnabaxy’s ANDA Products before expiration of the ’737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the ’737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce physicians and patients to infringe the ’737 Patent by performing all of the recited steps of one or more of claims 1 – 6 of the ’737 Patent.

75. Any such launch by Ranbaxy of its ANDA Products before expiration of the ’737 Patent would cause Endo to suffer immediate and irreparable harm.

ENDO’S COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’737 PATENT

76. Endo incorporates each of paragraphs 1-44 and 71-75 above as if set forth fully herein.

77. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

78. There is an actual case or controversy such that the Court may entertain Endo's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

79. Ranbaxy has made and will continue to make substantial preparation in the United States to manufacture, offer to sell, sell and/or import Ranbaxy's ANDA Products before expiration of the '737 Patent.

80. Ranbaxy's actions indicate its intention to manufacture, offer to sell, and sell Ranbaxy's ANDA Products before expiration of the '737 Patent, and further indicate a refusal to change the course of its action in the face of acts by Endo.

81. Any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's ANDA Products before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce physicians and patients to infringe the '737 Patent by performing all of the recited steps of one or more of claims 1 – 6 of the '737 Patent.

82. Endo is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's ANDA Products by Ranbaxy before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent.

ENDO AND MALLINCKRODT'S COUNT VII:
INFRINGEMENT OF THE '779 PATENT

83. Endo and Mallinckrodt incorporate each of paragraphs 1-44 above as if set forth fully herein.

84. The submission of Ranbaxy's ANDA No. 20-4527 to FDA constitutes infringement of the '779 Patent under 35 U.S.C. § 271(e)(2)(A).

85. Ranbaxy is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before expiration of the '779 Patent. On information and belief, if granted approval, Ranbaxy intends to launch Ranbaxy's ANDA Products before expiration of the '779 Patent.

86. Any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's ANDA Products before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent under 35 U.S.C. § 271(a)-(c).

87. Any launch by Ranbaxy of its ANDA Products before expiration of the '779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

88. Upon information and belief, Defendants are aware of the existence of the '779 Patent, and are aware that the commercial manufacture, sale, and offer for sale of Ranbaxy's ANDA Products constitutes infringement of the '779 Patent.

ENDO AND MALLINCKRODT'S COUNT VIII:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '779 PATENT

89. Endo and Mallinckrodt incorporate each of paragraphs 1-44 and 83-88 above as if set forth fully herein.

90. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

91. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

92. Ranbaxy has made and will continue to make substantial preparation in the United States to manufacture, offer to sell, and sell Ranbaxy's ANDA Products before expiration of the '779 Patent.

93. Ranbaxy's actions indicate its intention to manufacture, offer to sell, sell and/or import Ranbaxy's ANDA Products before expiration of the '779 Patent.

94. Any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's ANDA Products before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent under 35 U.S.C. § 271(a)-(c).

95. Any launch by Ranbaxy of its ANDA Products before expiration of the '779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

96. Plaintiffs are entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Ranbaxy's ANDA Products by Ranbaxy before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Endo and Mallinckrodt respectfully request the following relief:

A. A judgment that Ranbaxy has infringed the '737 Patent, and a declaration that Ranbaxy's commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the '737 Patent;

B. A declaration that the '737 Patent is valid and enforceable;

C. A judgment that Ranbaxy has infringed the ’779 Patent, and a declaration that Ranbaxy’s commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the ’779 Patent;

D. A declaration that the ’779 Patent is valid and enforceable;

E. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Ranbaxy’s ANDA No. 20-3506 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the ’737 and ’779 Patents, including any extensions;

F. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Ranbaxy’s ANDA No. 20-4527 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the ’737 and ’779 Patents, including any extensions;

G. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining Ranbaxy, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the ’737 and ’779 Patents for the full terms thereof, including any extensions;

H. An order that damages or other monetary relief be awarded to Plaintiffs if Ranbaxy engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Ranbaxy’s ANDA Products, or in inducing such conduct by others, prior to the expiration of the ’737 and ’779 Patents, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that any such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

I. Reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Endo in this action; and

J. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Julia Heaney

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